

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 15-22 are currently under consideration. Claim 15 is amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

The amendment to claim 15 is to clarify the extract in the recited topical formulation. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled.

II. THE REJECTION UNDER 35 U.S.C. § 102 IS OVERCOME

Initially, Applicants respectfully point out that “[a] rejection for anticipation under Section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.” *In re Buszard* 504 F.3d 1364, 1366 (Fed. Cir. 2007) (citing *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001) (“Invalidity on the ground of ‘anticipation’ requires lack of novelty of the invention as claimed . . . that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim.”)).

§ 102(b) in view of Park (KR 2001/028519)

Claims 15 and 22 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Park (KR 2001/028519). The rejection is traversed.

Applicants draw attention to instant claim 15, which recites “[a] method for treating acne, comprising administering to a subject in need of such acne treatment a topical formulation which

comprises extract obtained from *Biota orientalis*.” In contrast, Park relates to a method comprising administering a topical formulation comprising extract from *Cavalia gladiata*. Park is silent as to the use of extract obtain from *Biota orientalis*. Therefore, Park fails to disclose each and every limitation of instant claim 15, as well as instant claim 22 that depends therefrom.

§ 102(b) in view of Abe (JP 07025746)

Claims 15 and 22 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Abe (JP 07025746). The rejection is traversed.

Applicants reiterate that instant claim 15 is directed to a method for treating acne, comprising administering to a subject in need of such acne treatment a topical formulation which comprises extract obtained from *Biota orientalis*. Abe, on the other hand, relates to a method of skin-whitening, and thereby does not teach a step of administering a topical formulation to a subject in need of **treating acne**. Hence, Abe fails to disclose each and every limitation of instant claim 15, as well as instant dependent claim 22.

Neither Park nor Abe therefore anticipate claims 15 and 22. Accordingly, Applicants request for reconsideration and withdrawal of the Section 102 rejections.

III. THE REJECTION UNDER 35 U.S.C. § 103 IS OVERCOME

§ 103(a) in view of Park (KR 2001/028519)

Claims 15, 16, 19, and 22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Park (KR 2001/028519). The rejection is traversed.

Again, Applicants draw attention to instant claim 15, which recites “[a] method for treating acne, comprising administering to a subject in need of such acne treatment a topical formulation which comprises extract obtained from *Biota orientalis*.” As noted above, Park relates to a method comprising administering a topical formulation comprising extract from *Cavalia gladiata* and is silent as to the use of extract obtain from *Biota orientalis*. One of ordinary skill in the art would not arrive at the claimed method involving a formulation comprising extract from *Biota orientalis* based on the teaching of *Cavalia gladiata* in Park. Therefore, Park does not render instant claim 15, or instant claims 16, 19, and 22 which depend therefrom, obvious.

§ 103(a) in view of Abe (JP 07025746)

Claims 15, 16, 19, and 22 were rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Abe (JP 07025746). The rejection is traversed.

Applicants initially remind that, for an invention to be obvious, a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.

Pharmastem Therapeutics, Inc. v. Viacell, Inc. 491 F.3d 1342, 1360 (2007) (quoting *KSR*, 127 S. Ct. 1727, 1740 (a combination of elements “must do more than yield a predictable result”; combining elements that work together “in an unexpected and fruitful manner” would not have been obvious)).

As discussed above, instant claim 15 is directed to a method for treating acne, comprising administering to a subject in need of such acne treatment a topical formulation which comprises extract obtained from *Biota orientalis*. With this in mind, Applicants assert that one of ordinary skill in the art would not arrive at instant claim 15 in view of Abe, which relates to a method of skin-whitening. Abe does not teach or suggest a step of administering the composition in Abe to a subject in need of acne treatment. Therefore, Abe does not render instant claim 15 obvious.

Furthermore, the skilled artisan would not have an expectation of success in making the invention of instant claim 15 based on Abe. The composition in Abe comprises extracts from *Gastrodia elata*, “karukeija,” *Biota orientalis*, *Kichiascoparia*, *Arecatachu*, *Phyllostachys nigra* leaves, *Geranium Thunbergii*, *Cassa angustifolia*, *Kadsura japonica*, *Chrysanthemum morifolium*, *Juglans regia*, “manjerikon,” and *Asarum heterotropoides*. There is no teaching or suggestion in Abe to particularly select *Biota orientalis* from among these other plant extracts and arrive at the invention of instant claim 15. Furthermore, it cannot be predicted whether *Biota orientalis* in particular would be effective in a formulation to treat acne. For at least these reasons described herein, Abe does not render instant claim 15, or dependent claims 16, 19, and 22, obvious.

Neither Park nor Abe therefore render claims 15, 16, 19, and 22 unpatentable. Accordingly, Applicants request for reconsideration and withdrawal of the Section 103 rejections.

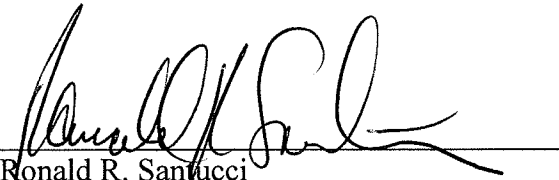
CONCLUSION

This application is in condition for allowance. Favourable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favourably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

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By:

A handwritten signature in black ink, appearing to read 'Ronald R. Santucci', is written over a horizontal line.

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